

**REMARKS/ARGUMENTS**

Claims 1-4, 6-8, 11-18, 20, 21, 23-25, and 28-32 are pending.

Rejection under 35 U.S.C. §102

Claims 1-4, 6-8, 11, 15, 17-18, 20-21, 23-25, 28 and 32 are rejected under 35 U.S.C. §102(b), as being anticipated by Lee (WO 01/21229 A1). Applicants respectfully traverse.

Independent claims 1 and 17 of the present invention are directed to a coated medical article comprising a coating with a first polymer and a polymeric additive. The polymeric additive has a degree of crystallinity greater than that of the first polymer and has a glass transition temperature of about -50 °C or greater. The Examiner asserts that the first polymers and polymeric additives of Lee are the same as those of the instant invention, it appears merely because they have the same name/formula, and thus would inherently possess the  $T_g$  and crystallinity requirements of claim 1 of the present invention. This is not a proper rejection for several reasons as outlined below.

The Examiner has not made a *prima facie* case of inherency. The first polymers and polymeric additives of the present invention and Lee are not necessarily the same as asserted by the Examiner on page 3 of the Office Action dated April 18, 2008. Applicant's have stated in the past responses, such as the reply dated 6/18/07, that the "degree of crystallinity . . . can be different for a [particular] polymer and depend upon the conditions under which the polymer is made and processed." As part of this Response, Applicants have attached two different articles showing that the crystallinity of poly(L-lactide) and poly(caprolactone) (PCL) can vary greatly. In the article titled "Poly(L-lactide) Microspheres with Controlled Crystallinity," the range of the degree of

crystallinity in the poly(L-lactide) microspheres was 0-60%. (Abstract, Polymer, vol. 42, No. 2, 637-643, 2001). In the article titled "Effect of Salt Leaching on PCL and PLGA(50/50) Resorbable Scaffolds" by Barbanti et al, the degree of crystallization of PCL was 40 to 60%. ([http://www.scielo.br/scielo.php?script=sci\\_arttext&pid=S1516-14392008000100014&lng=e&nrm=iso&tlng=e](http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1516-14392008000100014&lng=e&nrm=iso&tlng=e).) Thus, it is impossible to know exactly what combinations of polymers with different crystallinity were used in Lee because there are clearly many different first polymers and polymeric additives with varying crystallinity available.

Under the law of inherency, "[i]nherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)) (original emphasis). Thus, the Examiner has not shown with any certainty that the polymers disclosed in Lee are not necessarily the same as those of the instant invention.

Therefore, the Examiner has failed to create a *prima facie* case of inherency and thus there is no burden on the Applicants to show how the polymers of the instant invention are different from those in Lee. Thus, claims 1 and 17 are not anticipated by Lee. Because claims 2-4, 6-8, 11, 15, 18, 20-21, 23-25, 28 and 32 depend from independent claim 1 or 17, they too are not anticipated by Lee. Reconsideration and withdrawal of the rejections are requested.

Claims 1-3, 6-8, 11-18, 20, 23-25, 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossiany et al. (EP 0 970,711 A2). Applicants respectfully traverse.

Independent claims 1 and 17 of the present invention are directed to a coated medical article comprising a coating with a first polymer and a polymeric additive. The polymeric additive has a degree of crystallinity greater than that of the first polymer and has a glass transition temperature of about -50 °C or greater. The Examiner asserts that the first polymers and polymeric additives of Hossainy are the same as those of the instant invention, it appears merely because they have the same name/formula, and thus would inherently possess the  $T_g$  and crystallinity requirements of claim 1 of the present invention. This is not a proper rejection for all of the reasons cited above for Lee, and the remarks are hereby incorporated herein.

As with the Lee reference, the Examiner has failed to create a *prima facie* case of inherency and thus there is no burden on the Applicants to show how the polymers of the instant invention are different from those in Hossainy. Thus, claims 1 and 17 are not anticipated by Hossainy. Because claims 2-3, 6-8, 11-16, 18, 20, 23-25, and 28 - 32 depend from independent claim 1 or 17, they too are not anticipated by Hossainy. Reconsideration and withdrawal of the rejections are requested.

Claims 1-3, 6-8, 11, 15, 17-18, 20, 23-25, 28 and 32 rejected under 35 U.S.C. 102(e) as being anticipated by DeSimone et al. (US 2004/0181271 A1). Applicants respectfully traverse.

Independent claims 1 and 17 of the present invention are directed to a coated medical article comprising a coating with a first polymer and a polymeric additive. The polymeric additive has a degree of crystallinity greater than that of the first polymer and has a glass transition temperature of about -50 °C or greater. The Examiner asserts that

the first polymers and polymeric additives of DeSimone are the same as those of the instant invention, it appears merely because they have the same name/formula, and thus would inherently possess the  $T_g$  and crystallinity requirements of claim 1 of the present invention. This is not a proper rejection for all of the reasons cited above for Lee, and the remarks are hereby incorporated herein.

As with the Lee reference, the Examiner has failed to create a *prima facie* case of inherency and thus there is no burden on the Applicants to show how the polymers of the instant invention are different from those in DeSimone. Thus, claims 1 and 17 are not anticipated by DeSimone. Because claims 2-3, 6-8, 11, 15, 18, 20, 23-25, 28 and 32 depend from independent claim 1 or 17, they too are not anticipated by DeSimone. Reconsideration and withdrawal of the rejections are requested.

Claims 1-3, 6-8, 11, 15, 17-18, 20, 23-25, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 2001/0014717 A1). Applicants respectfully traverse.

Independent claims 1 and 17 of the present invention are directed to a coated medical article comprising a coating with a first polymer and a polymeric additive. The polymeric additive has a degree of crystallinity greater than that of the first polymer and has a glass transition temperature of about  $-50\text{ }^{\circ}\text{C}$  or greater. The Examiner asserts that the first polymers and polymeric additives of Hossainy '717 are the same as those of the instant invention, it appears merely because they have the same name/formula, and thus would inherently possess the  $T_g$  and crystallinity requirements of claim 1 of the present

invention. This is not a proper rejection for all of the reasons cited above for Lee, and the remarks are hereby incorporated herein.

As with the Lee reference, the Examiner has failed to create a *prima facie* case of inherency and thus there is no burden on the Applicants to show how the polymers of the instant invention are different from those in Hossainy '717. Thus, claims 1 and 17 are not anticipated by Hossainy'717. Because claims 2-3, 6-8, 11, 15, 18, 20, 23-25, 28 and 32 depend from independent claim 1 or 17, they too are not anticipated by Hossainy '717. Reconsideration and withdrawal of the rejections are requested.

**CONCLUSION**

Removal of the rejections and allowance of the claims is respectfully requested. Should the Examiner have any questions regarding this communication or any proposals with respect to the claims, the Examiner is invited to contact Robert Auerbach at (415) 954-00315.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

Date: July 18, 2008  
Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0315  
[rauerbach@ssd.com](mailto:rauerbach@ssd.com)

/RPA/  
Robert P. Auerbach  
Attorney for Applicants  
Reg. No. 46,525

APPENDIX

“Poly(L-lactide) Microspheres with Controlled Crystallinity”

“Effect of Salt Leaching on PCL and PLGA(50/50) Resorbable Scaffolds”